



Atty. Dkt. No. 065691-0339  
Appl. Ser. No. 10/689,469

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DEBREGEAS et al.  
Title: GRANULES CONTAINING A  
PLANT SUBSTANCE AND  
PROCESS FOR PREPARING  
THEM  
Appl. No.: 10/689,469  
Filing Date: 10/20/2003  
Examiner: Unassigned  
Art Unit: Unassigned

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TRANSMITTAL

Mail Stop Application  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Enclosed are:

- ☒ [ X ] Information Disclosure Statement Under 37 CFR § 1.56 (4 pages)
- ☒ [ X ] PTO Form SB08 (1 page)

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 06-1447. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1447.

Respectfully submitted,

Date 11/20/03

By M. Scott McBride

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**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.56**

Mail Stop Application  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 C.F.R. §1.56. Copies of the documents listed on the Form PTO/SB/08 are not being provided because these documents were previously cited to the United States Patent & Trademark Office in the parent application. If the Examiner would like the Applicants to provide additional copies of any of the listed documents for the file of the present application, Applicants will be happy to do so upon request.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 C.F.R. §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 C.F.R. §1.97(b)(3), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

Any document listed on the attached form PTO/SB/08 was cited as being relevant during the prosecution of the corresponding parent application, 09/312,485; the international application (PCT/FR00/01316) of which 09/312,485 is a national stage entry; or the foreign priority application (FR 99 03075). English-language summaries are provided for EP 0 290 299, DE 2458112, FR 1443063, and FR 2 616 068 below. U.S. 5,876,758 is an English-language counterpart for WO 93/12761, and U.S. 5,965,165 is an English-language counterpart for FR 2 737 134. The absence of a translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 C.F.R. §1.98 and MPEP § 609).

**EP 0 290 299**

This application relates to a process for the preparation of water-soluble pellets containing Ginkgo biloba extract, wherein the pellets are prepared by granulating a mixture that comprises the active principle and a water-soluble support.

**DE 2458112**

This application relates to micropellets comprising an active principle, which may be ipeca extract, and a saccharose as a binder.

FR 1 443 063

This application relates to a Theophylline formulation, comprising a neutral core coated with a layer containing Theophylline, an adjuvant which may be a thyme extract, and a mixture of glyceride, oily alcohol and beeswax.

FR 2 616 068

As indicated in an English language abstract, the application relates to

"[t]herapeutically active plant extracts are stabilised by coating them with a matrix-forming material (A): granulating the resulting mixt. with a volatile solvent; drying the granules, and incorporating, after crushing, into a pharmaceutically-acceptable, non-toxic, inert excipient. Where the extract is dry material, the matrix is methylcellulose; where it is a soft material, the matrix is micronized silica. USE ADVANTAGE – The method is esp. used to stabilize heteroside-contg. extracts, esp. those from the hawthorn. The compsn., which may include a complementary or synergistic component, can now be stored for a long time without a significant loss of active ingredient."

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 06-1447. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 06-1447.

Respectfully submitted,

Date 11/20/03

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Substitute for form 1449B/PTO

NOV 24 2003

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: November 20, 2003

(Use as many sheets as necessary)

Sheet 1 of 1

## Complete if Known

Application Number	10/689,469
Filing Date	10/20/2003
First Named Inventor	Debregeas et al.
Group Art Unit	TBD
Examiner Name	TBD
Attorney Docket Number	065691-0339

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A1	U.S. 6,120,621		Breitenbach et al.	09-19-2000	
	A2	U.S. 6,056,949		Menzi et al.	05-02-2000	
	A3	U.S. 6,030,621		De Long et al.	02-29-2000	
	A4	U.S. 5,965,165		Zannini et al.	10-12-1999	
	A5	U.S. 5,876,758		Meybeck et al.	03-02-1999	
	A6	U.S. 5,733,551		Jacob et al.	03-31-1998	
	A7	U.S. 5,427,800		Cingotti et al.	06-27-1995	
	A8	U.S. 5,104,661		Lau et al.	04-14-1992	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A9		EP 0290 299 A1		Pierre Fabre Medicament	11-09-1988		
	A10		EP 0687 466 A1		Tapuach Natural Technologies Ltd.	12-20-1995		
	A11		DE 2 458 112 A1		Dr. Wilhelm Hurka	02-05-1976		
	A12		FR 2 616 068		Bonnaud et al.	12-09-1988		
	A13		FR 1 443 063		Key Pharmaceuticals Inc.	05-16-1966		
	A14		WO 98/16111		Shaman Pharmaceuticals, Inc.	04-23-1998		
	A15		WO 93/12761		Lvmh Recherche	07-08-1993		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A16	International Search Report for PCT/FR00/01316; filed 05-17-2000	
	A17	International Preliminary Examination Report for PCT/FR00/01316; filed 05-17-2000	
	A18	Websters Dictionary, pp 331, 792 (Riverside Publishing, 1992).	

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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